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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,170	04/16/2004	Ciaran N. Cronin	SYR-HDAC-5004-C1	8535
32793	7590	09/05/2006	EXAMINER	
TAKEDA SAN DIEGO, INC. 10410 SCIENCE CENTER DRIVE SAN DIEGO, CA 92121			STEADMAN, DAVID J	
			ART UNIT	PAPER NUMBER
			1656	

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/826,170	Applicant(s) CRONIN ET AL.	
	Examiner David J. Steadman	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,8,10-12,25,26,28-31,44-47 and 49-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7,8,10-12,25,26,28-31,44-47 and 49-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 April 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Appendices A, B, and C</u> |

DETAILED ACTION

Status of the Application

- [1] Claims 7-8, 10-12, 25-26, 28-31, 44-47, and 49-52 are pending in the application.
- [2] Applicant's amendment to the claims, filed on 6/19/2006, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.

Election/Restriction

- [3] Applicant's election without traverse of Group II, original claims 7-12, 15-17, 25-31, and 43-44, in the response filed on 6/19/2006 is acknowledged. Claims 45-47 and 49-52, while not included in the claim groupings in the restriction mailed on 5/16/2006, are now amended to depend from the claims of the elected invention and will be co-examined herein.

Information Disclosure Statement

- [4] The examiner can find no information disclosure statement (IDS) in the application file. If the examiner has inadvertently overlooked an IDS that has been filed in the instant application, applicant's cooperation is requested in alerting the examiner to this IDS in the response to this Office action.

Drawings

- [5] The drawings are objected to because Figures 1 and 3 are not numbered in accordance with 37 CFR 1.84(u)(1), which states, "[p]artial views intended to form one

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complete view, on one or several sheets, must be identified by the same number followed by a capital letter." A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Sequence Compliance

[6] This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825; applicants' attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). To be in compliance, applicants should identify nucleotide sequences of at least 10 nucleotides and amino acid sequences of at least 4 amino acids in the specification by a proper sequence identifier, i.e., "SEQ ID NO:" (see MPEP 2422.01). If these sequences have not been listed in the computer readable form and paper copy of the sequence listing, applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing", an initial paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification, and a statement that the content of the paper and CRF copies are the same and, where applicable, include no new matter as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d). See particularly Figure 3 of the specification containing a list of atomic coordinates representing the

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disclosure of an amino acid sequence, and therefore the Figure should have a heading identifying the amino acid sequence in the Figure. See also p. 15, paragraph [0063].

Claim Objections

[7] Claims 11 and 29 are objected to as using inconsistent terminology. Claim 11 recites the space group "P212121" and claim 29 recites the space group "P2₁2₁2₁." It is suggested that applicant use consistent terms throughout the claims.

[8] Claim 50 is objected to as not ending in a period.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[9] Claim(s) 10, 28, 45-47, and 49-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

[a] Claims 10 and 28 are indefinite in the recitation of "resolution less than 3.0 Angstroms" as it is unclear as to whether the term "less than" is meant to limit the resolution or Angstrom value. It is well-known in the art that the resolution of diffraction for a protein crystal is inversely related to the Angstrom value. In this case, it is unclear as to whether the term "resolution less than 3.0 Angstroms" is meant to be interpreted as meaning a better resolution than that obtained at 3.0 Angstroms, or whether the term

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is meant to be interpreted as meaning a lower resolution than that obtained at 3.0 Angstroms. It is suggested that applicant clarify the meaning of the claims.

[b] Claim 45 (claims 46-47 and 49-52 dependent therefrom) recites a method step of "performing rational drug design using the solved structure." Neither the specification nor the claims define the term "rational drug design" and it is unclear as to the intended method step(s) that is/are encompassed by the term, e.g., is the method step intended as being a mental step, requiring no active method step(s), is the method step intended to encompass active method steps, or is the method intended to encompass both active and mental steps? If the recitation of "rational drug design" is intended as encompassing active method steps, it is unclear as to what steps are encompassed. Consequently, it is unclear as to how a skilled artisan performs "rational drug design" in accordance with the claim. It is suggested that applicant clarify the meaning of the term "rational drug design."

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

[10] Claim(s) 8, 10, 26, 28, and 46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time

the application was filed, had possession of the claimed invention. This is a new matter rejection.

MPEP § 2163 states, "when filing an amendment an applicant should show support in the original disclosure for new or amended claims" (MPEP 8th Ed., October 2006 Revision at pp. 2100-176 and 2100-183) and "[i]f the originally filed disclosure does not provide support for each claim limitation, or if an element which applicant describes as essential or critical is not claimed, a new or amended claim must be rejected under 35 U.S.C. 112, para. 1, as lacking adequate written description".

Claims 8, 26, and 46 have been amended to require that the protein "crystallizes as a trimer." Applicant fails to "show support" for the newly added limitation and the examiner can find no support for the amendment as recited in the claims.

Claims 10 and 28 have been amended to recite the crystal diffracts x-rays to a resolution "less than 3.0 Angstroms." Previously, the claims recited the crystal diffracts x-rays to a resolution "greater than 3.0 Angstroms." Applicant fails to "show support" for the newly added limitation and the examiner can find no support for the amendment as recited in the claims.

Applicant is invited to show support in the original application for the limitations at issue.

[11] Claim(s) 7-8, 10-12, 25-26, 28-31, 45-47, and 49-52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that

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the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a composition comprising SEQ ID NO:5 in crystalline form, a method of making said crystal, and optionally solving the three-dimensional structure, and performing rational drug design to identify an entity that associates with the protein or protein crystal, optionally measuring or comparing an activity of the protein or a phenotype of cells expressing the protein.

For claims drawn to a genus, MPEP § 2163 states the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, *i.e.*, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. MPEP § 2163 further states that a "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. In this case, the specification discloses only a single representative species of the genus of claimed crystals, *i.e.*, a crystal of purified SEQ ID NO:5 in complex with TSA and Zn^{++} having the space group symmetry $P2_12_12_1$ and having vector lengths $a=92.1 \text{ \AA}$, $b=97.6 \text{ \AA}$, and $c=138.9 \text{ \AA}$ and $\alpha=\beta=\gamma=90^\circ$ that diffracts x-rays to a resolution of 1.84 \AA and has three

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molecules of SEQ ID NO:5 in complex with TSA and Zn^{++} per asymmetric unit (p. 28, Table 6B and paragraph [0118]); the specification discloses only a single representative species of the genus of crystallization methods, *i.e.*, the method disclosed at p. 52 of the specification; the specification discloses only a single representative species of crystal structures of SEQ ID NO:5, *i.e.*, the 3-D structure of SEQ ID NO:5 having the structural coordinates of Figure 3; the specification discloses only a single representative species of methods of "rational drug design," *i.e.*, using the structure of SEQ ID NO:5 having the structural coordinates of Figure 3 to perform a fitting operation between an entity and the computer model and analyzing the results of the fitting operation to quantify the association between the entity and the model; and discloses only a single representative species of activities of the protein or a cell expressing the protein that can be measured, *i.e.*, histone deacetylase activity. Other than these single disclosed species, the specification fails to describe any additional representative species of the recited genus, which encompasses widely variant species, including crystals of polypeptides that are widely variant in space group and unit cell dimensions that are unliganded or have any bound ligand, are produced by essentially any method of crystallization, any 3-D conformation of SEQ ID NO:5, including homology models with any bound ligand, any methods considered to be "rational drug design," and any measurable "activity" of a protein of SEQ ID NO:5 or a cell expressing SEQ ID NO:5. In this case, the art of protein crystallization, structure determination, and rational drug design are highly unpredictable (see discussion below specifically addressing unpredictability). MPEP § 2163 states "[f]or inventions in an unpredictable art, adequate

written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus." As such, the single disclosed species of each genus as noted above fails to describe all members of each genus as encompassed by the claims.

Given the lack of description of a representative number of species, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

[12] Claims 7-8, 10-12, 25-26, 28-31, 45-47, and 49-52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a crystal of purified SEQ ID NO:5 in complex with TSA and Zn^{++} having the space group symmetry $P2_12_12_1$ and having vector lengths $a=92.1 \text{ \AA}$, $b=97.6 \text{ \AA}$, and $c=138.9 \text{ \AA}$ and $\alpha=\beta=\gamma=90^\circ$ that diffracts x-rays to a resolution of 1.84 \AA and has three molecules of SEQ ID NO:5 in complex with TSA and Zn^{++} per asymmetric unit, a method for crystallization thereof at p. 52 of the specification, using the 3-D structure of SEQ ID NO:5 having the structural coordinates of Figure 3 to perform a fitting operation between an entity and the computer model and analyzing the results of the fitting operation to quantify the association between the entity and the model, and determining the effect of said entity by comparing the histone deacetylase activity of SEQ ID NO:5 or a cell expressing SEQ ID NO:5 in the presence and absence of the entity, does not reasonably provide enablement for all crystals, methods of crystallization, 3-D structures

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and uses thereof in "rational drug design," and activities of SEQ ID NO:5 or a cell expressing SEQ ID NO:5 that are measurable as broadly encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

It is the examiner's position that undue experimentation would be required for a skilled artisan to make the entire scope of the claimed invention. Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)) as follows: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. See MPEP § 2164.01(a). The Factors most relevant to the instant rejection are addressed in detail below.

The breadth of the claims: The claims are so broad as to encompass: crystals of SEQ ID NO:5 that are unliganded or have any bound ligand, wherein the crystals have any space group, and/or any unit cell dimensions, essentially any method of crystallization thereof, any 3-D conformation of SEQ ID NO:5, including homology models of unliganded or ligand-bound polypeptides, any methods considered to be "rational drug design," and any measurable "activity" of a protein of SEQ ID NO:5 or a cell expressing SEQ ID NO:5. The broad scope of the claims is not commensurate with the enablement

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provided by the disclosure. In this case the disclosure is limited to a crystal of purified SEQ ID NO:5 in complex with TSA and Zn^{++} having the space group symmetry $P2_12_12_1$ and having vector lengths $a=92.1 \text{ \AA}$, $b=97.6 \text{ \AA}$, and $c=138.9 \text{ \AA}$ and $\alpha=\beta=\gamma=90^\circ$ that diffracts x-rays to a resolution of 1.84 \AA and has three molecules of SEQ ID NO:5 in complex with TSA and Zn^{++} per asymmetric unit, a method for crystallization thereof at p. 52 of the specification, using the 3-D structure of SEQ ID NO:5 having the structural coordinates of Figure 3 to perform a fitting operation between an entity and the computer model and analyzing the results of the fitting operation to quantify the association between the entity and the model, and determining the effect of said entity by comparing the histone deacetylase activity of SEQ ID NO:5 or a cell expressing SEQ ID NO:5 in the presence and absence of the entity.

The state of the prior art; The level of one of ordinary skill; and The level of predictability

in the art: The state of the art at the time of the invention acknowledges a **high** level of unpredictability for making a protein crystal with an expectation that it is diffraction-quality. Branden et al. ("Introduction to Protein Structure Second Edition", Garland Publishing Inc., New York, 1999) teaches that "[c]rystallization is usually quite difficult to achieve" (p. 375) and that "[w]ell-ordered crystals...are difficult to grow because globular protein molecules are large, spherical, or ellipsoidal objects with irregular surfaces, and it is impossible to pack them into a crystal without forming large holes or channels between the individual molecules" (p. 374). Also, Drenth ("Principles of X-ray Crystallography," Springer, New York, 1995) teaches that "[t]he science of protein crystallization is an underdeveloped area" and "[p]rotein crystallization is mainly a trial-

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and-error procedure" (p. 1). One cannot predict *a priori* those conditions that will lead to the successful crystallization of a diffraction-quality crystal nor can one predict the space group symmetry or unit cell dimensions of the resulting crystal. See Kierzek et al. (*Biophys Chem* 91:1-20, 2001), which teaches that "each protein crystallizes under a unique set of conditions that cannot be predicted from easily measurable physico-chemical properties" and that "crystallization conditions must be empirically established for each protein to be crystallized" (underline added for emphasis, p. 2, left column, top). Thus, in view of these teachings, a skilled artisan would recognize that it is highly unpredictable as to whether diffraction-quality crystals of other HDAC2 polypeptides optionally having a desired space group and unit cell dimensions as encompassed by the claims can be achieved using *any* crystallization parameters. Regarding the use of homology models for use in rational drug design, Lambert et al. (US Patent Application Publication 2004/0137518) acknowledges that "[p]otential or existent homology models cannot provide the necessary degree of specificity" in the *in silico* design of modulators (p. 3, ¶[0017]).

The amount of direction provided by the inventor; The existence of working examples:

The specification discloses the utility of the claimed crystal is in the determination of the 3-D structure of HDAC2 and interacting molecules (p. 1, ¶[004]), which, as acknowledged by Branden et al. (*supra*) at p. 374, requires a diffraction-quality crystal. In this case, the specification discloses only a single working example of such a diffraction quality crystal, *i.e.*, a crystal of purified SEQ ID NO:5 in complex with TSA and Zn⁺⁺ having the space group symmetry P2₁2₁2₁ and having vector lengths a=92.1

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Å, $b=97.6$ Å, and $c=138.9$ Å and $\alpha=\beta=\gamma=90^\circ$ that diffracts x-rays to a resolution of 1.84 Å and has three molecules of SEQ ID NO:5 in complex with TSA and Zn^{++} per asymmetric unit; the specification discloses only a single working example of a method for successfully crystallizing the protein of SEQ ID NO:5, *i.e.*, the method disclosed at p. 52 of the specification; the specification discloses only a single working example of crystal structures of SEQ ID NO:5, *i.e.*, the 3-D structure of SEQ ID NO:5 having the structural coordinates of Figure 3; the specification discloses only a single working example of methods of "rational drug design," *i.e.*, using the structure of SEQ ID NO:5 having the structural coordinates of Figure 3 to perform a fitting operation between an entity and the computer model and analyzing the results of the fitting operation to quantify the association between the entity and the model; and discloses only a single working example of activities of the protein or a cell expressing the protein that can be measured, *i.e.*, histone deacetylase activity. Other than these working examples, the specification fails to provide guidance regarding crystals, methods for crystallization, crystal structures, methods of rational drug design, and other activities of SEQ ID NO:5 or cells expressing SEQ ID NO:5 as encompassed by the claims.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure: While methods of protein crystallography were known at the time of the invention, it was not routine in the art to screen all polypeptide complexes of SEQ ID NO:5 as encompassed by the claims for those that will yield diffraction-quality crystals using any crystallization conditions as encompassed by the claims and to determine those polypeptides that represent biologically-relevant HDAC2 structures.

In view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, the high level of unpredictability as evidenced by the prior art, and the amount of experimentation required to make and use all crystals and polypeptides as broadly encompassed by the claims, undue experimentation would be necessary for a skilled artisan to make and use the entire scope of the claimed invention. Thus, applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application

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filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

[13] Claim 44 is rejected under 35 U.S.C. 102(e) as being anticipated by Venter (US Patent 6,812,339). The claim is drawn to a composition comprising a protein consisting of SEQ ID NO:5. MPEP 2111.01 states, “[d]uring examination, the claims must be interpreted as broadly as their terms reasonably allow.” In this case, the examiner has interpreted a “composition” as being inclusive of a polypeptide. Thus, claim 44 has been interpreted as a polypeptide comprising a protein consisting of SEQ ID NO:5.

The reference of Venter et al. teaches a polypeptide, SEQ ID NO:2474, that comprises SEQ ID NO:5 herein (see Appendices A and B). This anticipates claim 44 as written.

[14] Claim 44 is rejected under 35 U.S.C. 102(b) as being anticipated by GenBank Accession Number Q92769, GI:3023939, February, 1998. The claim is drawn to a composition comprising a protein consisting of SEQ ID NO:5. MPEP 2111.01 states, “[d]uring examination, the claims must be interpreted as broadly as their terms reasonably allow.” In this case, the examiner has interpreted a “composition” as being inclusive of a polypeptide. Thus, claim 44 has been interpreted as a polypeptide comprising a protein consisting of SEQ ID NO:5.

GenBank Accession Number Q92769 teaches a polypeptide that comprises SEQ ID NO:5 herein (see Appendix C). This anticipates claim 44 as written.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

[15] Claim 44 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim drawn to a "composition comprising a protein consisting of SEQ ID NO:5." As noted above, the term "composition" has been broadly interpreted as being inclusive of a polypeptide. The claim reads on a product of nature and should be amended to indicate the hand of the inventor, e.g., by insertion of "purified" or "isolated." See MPEP § 2105.

Citation of Relevant Art

[16] The art made of record and not relied upon is considered pertinent to applicant's disclosure: Wang et al. (*J Med Chem* 48:6936-6947, 2005) teaches a homology model of HDAC2 using the 3-D structure of HDLP as a template (p. 6937, right column, bottom). The reference of Wang et al. does not teach a crystal of HDAC2 and because of its post-filing publication date, is not available as prior art under 35 U.S.C. 102.

Conclusion

[17] Status of the claims:

Claims 7-8, 10-12, 25-26, 28-31, 44-47, and 49-52 are pending.

Claims 7-8, 10-12, 25-26, 28-31, 44-47, and 49-52 are rejected.


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No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656